IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMACEUTICALS INC. and SANOFI-AVENTIS US LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 06-286 (GMS)
BARR LABORATORIES, INC.	)	
Defendant.	)	

DEFENDANT BARR LABORATORIES, INC.'S POST-TRIAL FINDINGS OF FACT AND CONCLUSIONS OF LAW

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INTRODUCTION

Barr is entitled to a judgment in its favor for several reasons. First, Aventis has failed to prove infringement because it never conducted *any* relevant testing on Barr's product. Aventis relied solely on wholly unreliable PET testing of its *own product*, which has a substantially lower viscosity and, thus, does nothing to prove that *Barr's product* reaches the frontal sinus. Nor did Aventis conduct any relevant testing to determine if Barr's product increases to unsheared viscosity after being deposited in the nasal cavity – which is wholly implausible because nasal cavity conditions (*e.g.*, high temperatures, fluid secretion, rapidly-beating cilia) make nasal sprays less viscous, not more viscous.

Second, Barr presented two leading nasal spray formulators to offer opinions on obviousness and nonenablement. In a development that – at least to Barr – was shocking, Aventis decided against calling *any* expert to offer *any* opinion on either obviousness or nonenablement. Invalidity is thus effectively undisputed.

Third, Aventis' patents are invalid based on prior public use because Aventis ran clinical trials in which about 600 patients used Nasacort AQ with no confidentiality obligations. Aventis' sole effort to avoid this defense – the experimental use exception – died when this Court held that Aventis was bound to its reduction-to-practice date of May 1992. Under black-letter law, experimental use does not apply after reduction to practice. Thus, again, invalidity is undeniable.

PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

I. Noninfringement: Barr's Product Does Not Reach The Frontal Sinus.

1. Aventis failed to prove by a preponderance of the evidence that Barr's product deposits on the frontal sinus, which is expressly required in '329 patent claim 26 and required by the Court's construction of '573 patent claim 6. PTX3 at 15:12-16:11; D.I. 130 ¶ 6.

2. Despite bearing the burden, Aventis never conducted *any* testing on Barr's product to determine whether it will reach the frontal sinus. 163:6-8. Instead, Aventis relied entirely on Dr. Marc Berridge's unfounded belief that Barr's product is "identical" to Nasacort AQ with the "same thixotropic properties and the same viscosities [as Nasacort AQ]." 144:21-24; 171:2-6. But that is not true. It is undisputed – based on Aventis' own testing – that Barr's product has a 60% higher shear viscosity than Nasacort AQ. 228:15-16; 229:6-230:13. Although Barr's product and Nasacort AQ have similar amounts of the same ingredients (though not identical), Aventis' viscosity expert, Dr. Robert Lochhead, explained that manufacturing conditions can impact viscosity profiles, even from one lot to the next. 228:10-229:10. And these viscosity profile differences can affect whether a product reaches the frontal sinus. 230:17-24; 231:5-7; 178:15-16; 179:3-5; 179:18-20; 514:2-5. Thus, Aventis' case fails because it never tested *Barr's* product.

3. Moreover, Dr. Ian Mackay testified, and Dr. Maureen Donovan confirmed, that it is "extremely unlikely, if not impossible" for a nasal spray like Barr's product to reach the frontal sinus. 342:20-23; 352:20-353:4; 399:22-401:4; 408:6-409:10; 419:25-420:6. Unlike any other witness, Dr. Mackay has intimate knowledge of the frontal sinus anatomy – he has performed about 1000 frontal sinus operations. 340:11-341:1; 354:10-356:8. And he explained that the pathway to the frontal sinus is a "very narrow, tortuous route." 342:25-343:3. To reach the frontal sinus, nasal spray droplets would have to avoid impacting on and thereby sticking to any mucosal surfaces, remain suspended in the air stream, pass through the turbinates, make a u-turn in mid-air, and then head up the long, tortuous and extremely narrow frontal sinus pathway, against the ciliary forces going down. 345:10-346:10; 346:22-24; 349:6-350:8; 353:9-18. That is simply not going to happen, as Dr. Mackay explained: "[F]or it to have to turn around and go

against gravity and back on itself and not touch anything either, because if it touches anything on the way it's going to stick and stay there, I just think it's completely impossible." 354:6-9; 356:7-8.

4. Aventis' own expert, Dr. Michael Kaliner, explained the gymnastics he uses to attempt to reach patients' frontal sinuses with liquids (not sprays). He stands patients on their heads, fills their nasal cavities with large volumes of fluid, and then hopes (because, to this day, he cannot prove) that some steroid will reach the frontal sinus. 98:8-104:23; 106:2-7.

5. Contrary to his own complicated procedure, Dr. Kaliner later testified in rebuttal that it would be easy for nasal sprays to reach the frontal sinus. 702:20-703:12. But, incredibly, his testimony was based on a *misreading* of a CT scan that *did not even show the frontal sinus*. 824:15-18. Aventis' other expert, Dr. Eli Meltzer, candidly conceded during cross examination, "I don't see the frontal sinus" on the very CT scan Dr. Kaliner relied on for his testimony. *Id.*

6. Dr. Berridge's PET studies confirm the virtual impossibility of reaching the frontal sinus. In 2002, Dr. Berridge determined that "[n]o uptake was observed in the frontal sinus" for the six volunteers in that study: "Q. . . . [Y]ou did come up with a conclusion about frontal sinus data. Right? A. I reported there was zero uptake. Q. So you did have some conclusions about the data in the 2002 study? A. Well, yes, it wasn't totally worthless, no." 162:25-163:5; DX 5; 443:20-25. And, as Dr. Barry Siegel testified, the results from the 1998 study comport completely with this conclusion because the miniscule frontal-sinus activity shown in three subjects was likely due to unavoidable PET measurement errors, not actual frontal sinus deposition. 446:15-17; 444:1-446:14; 446:18-447:6.

7. Because the 1998 and 2002 studies prove Barr's point, Aventis relied on a flawed 1996 study Dr. Berridge conducted using cubical regions to assign radioactivity to the frontal

sinus – radioactivity that was likely present in a different part of the nasal anatomy. 435:20-436:2; 436:24-437:25; 438:13-20; 447:10-16. The flaw in his cubical region method is proven by his 1996 study showing that 3-4% of the steroid hits the frontal sinus – an amount completely contradicted by no frontal sinus deposit in the purportedly "reliable" 1998 study. 446:15-17; 447:7-16.

8. Dr. Berridge even admitted that he misassigned radioactivity in the 1996 study due to the use of the imprecise cubical regions. 154:19-155:1; 155:24-156:1. Yet, until this litigation, he never disclosed that misassignment to anyone. 156:25-157:4; 157:20-23; 158:3-18; 162:6-19; 447:10-16; 464:16-465:11; DX 6; DX 66. As Dr. Siegel concluded, "the substantial majority of the scientific evidence" shows no "deposit on the frontal sinus." 448:21-449:2.

9. But, even if this Court were to accept *all* of Aventis' assertions, Barr still does not infringe as a matter of law because there is no showing of direct, contributory or induced infringement. Barr obviously does not directly infringe either asserted claim because it does not administer its product to any patients – they administer it. Barr also does not contributorily infringe because, even under Aventis' most optimistic view of the evidence based solely on the 1996 and 1998 studies, 25% of subjects experience no frontal sinus deposit. 334:2-7. This is a substantial noninfringing use, which by definition cannot constitute contributory infringement. 35 U.S.C. § 271(c); *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1374 (Fed. Cir. 2003); *C.R. Bard v. Advanced Cardiovascular Sys.*, 911 F.2d 670, 674 (Fed. Cir. 1990).

10. Moreover, Aventis' only, manufactured excuse for disregarding the 2002 study – that the nasal spray was subjected to cold weather, 178:5-179:20 – is yet *another* noninfringing use because Barr's product can be used in cold weather. Thus – again accepting all of Aventis' assertions – at least eight of the fourteen subjects showed no frontal sinus deposit. 147:12-20.

11. Finally, Aventis failed to offer any evidence whatsoever on induced infringement. Aventis did not even attempt to prove that Barr has actual knowledge that frontal sinus deposit occurs, which is a required showing for induced infringement. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003); *Jansen v. Rexall Sundown*, 342 F.3d 1329, 1334 (Fed. Cir. 2003) (conjecture that some patients might meet claim elements is insufficient).

II. Noninfringement: Barr's Product Does Not Return To Unsheared Viscosity After Being Sprayed Into The Nose.

12. Aventis also did not prove that Barr's product when deposited in the nose would return to a viscosity of 400 to 800 centipoise, which is expressly required in '573 patent claim 6, or to unsheared viscosity, which is required in '329 patent claim 26 by the Court's construction of "thixotropic." PTX1 at 13:39-43; D.I. 130 ¶¶ 2, 4.

13. The Federal Circuit has specifically held that *in vitro* or "table top" testing cannot be used to prove infringement of a claim that requires *in vivo* (*i.e.*, in the body) results "absent evidence that the *in vitro* system is a good model of actual *in vivo* behavior." *See Alza Corp. v. Mylan Labs.*, 464 F.3d 1286, 1297 (Fed. Cir. 2006).

14. Yet, Aventis *never* conducted any such testing. It literally did *nothing* to simulate the environment in the nasal cavity. 413:2-18. It never tested whether Barr's product would, within the mere 30 minutes or so that the patent reports it remains in the nasal cavity, return to unsheared viscosity at the temperature of the nasal cavity (about 98.6° F), while mixing with other fluids (the nose produces two quarts of mucus per day) and while being subjected to shear forces of cilia (they beat 1,000 times per minute). 410:14-411:1; 411:5-413:1; 414:2-15; 416:9-417:3; PTX1 at 1:53-57.

15. Dr. Lochhead, the only Aventis expert to test Barr's product, did testing *in vitro* – in a Griffin beaker on a table top. 208:15-17; 209:7-21. Although he easily could have done so,

he did not even test whether Barr's product – *on the table top* – would return to unsheared viscosity within 30 minutes. 215:23-216:19; 495:21-496:21; 285:9-14.

16. To the contrary, Aventis' own testing with Nasacort AQ shows that Nasacort AQ takes *more than five days* to return to unsheared viscosity and *24 hours* to climb back up to half of its unsheared viscosity. 497:10-499:21; DX 23 at 97; *see also* 538:1-16. Indeed, as Dr. Lochhead admitted and Dr. Daniel Klingenberg explained, Dr. Lochhead's own testing of Barr's product showed virtually no recovery after sitting for three minutes. 494:21-495:17; 499:6-21; 283:22-25; 215:15-22. And Dr. Lochhead himself let Barr's product sit for a full 48 hours before measuring unsheared viscosity, which shows he does not think it could possibly return to unsheared viscosity in a mere 30 minutes. 213:15-20.

17. If it takes hours and even days to return to unsheared viscosity *on the table top*, there is simply no possible way Barr's product would do so in 30 minutes *in the nasal cavity*. 417:4-10; 220:9-17. As Dr. Donovan explained, the environment in the nasal cavity would make Barr's product less viscous, not more viscous. 410:14-413:1; 414:2-417:3. Dr. Lochhead admitted the same thing: "Q. Nasal fluids can also impact the viscosity of a formulation. Isn't that true? A. I don't know. I haven't measured it. But I surmise it's true." 222:22-25. Even the inventor himself, Dr. Soo-Il Kim, admitted that viscosity would fall if the claimed nasal sprays were subjected to increased temperatures, moisture or humidity. Kim Dep. Tr. at 126:17-18; 126:22-24; 127:3-4; 146:14-147:2; 147:14-148:1; 148:16, 148:19-20; 222:6-15; 276:2-18.

18. To combat all of this, Aventis relied solely on Dr. Robert Prud'homme. But until the day before he testified, Dr. Prud'homme had *no opinion* on whether Barr's product returns to unsheared viscosity in the nasal cavity: "[Y]ou don't know one way or the other in the nose whether once applied the shear returns to unsheared for any of the nasal sprays that we are

talking about today. Right? Answer: I am not an expert in nasal passages and have no opinion in that area." 278:3-19; 277:10, 276:2-18.

19. Despite that acknowledged lack of expertise, Dr. Prud'homme performed calculations during trial (which he still has not disclosed) that he claimed showed that Barr's product would sit – remaining undisturbed without any mixing – on an mucus blanket that acts as a conveyor belt to send the product out of the nasal cavity. 292:5-23; 293:24-294:22. This, he claims, would enable Barr's product to return to unsheared viscosity in 30 minutes.

20. There are multiple problems with this belated conveyor belt theory. First, Dr. Donovan – an actual expert in nasal cavity conditions – testified that the water-based nasal spray formulation would obviously mix with water-based mucus. 411:5-413:1; 414:16-416:5. That mixing would bring the formulation in contact with shear-inducing cilia. 414:2-15; 416:9-13. Second, as Dr. Donovan also explained, if the formulation did not mix with mucus but was whisked away by a "conveyor belt," the nasal spray would be useless because it needs to reach the cells underlying the mucus to have any medicinal effect. 415:20-416:5. Third, Dr. Prud'homme failed to disclose or even explain his calculations and failed to address all but two of the formulation excipients in Barr's product. 293:24-294:22; *Arthur A. Collins, Inc. v. N. Telecom Ltd.*, 216 F.3d 1042, 1046 (Fed. Cir. 2000) (expert's unsupported conclusion on infringement is insufficient).

21. Dr. Prud'homme also relied on two reports on Nasacort AQ – neither of which mimicked nasal conditions or reflected testing with Barr's product. 278:22-279:25; 280:2-25. Contrary to his suggestion, neither report shows that Nasacort AQ recovers 90% of its unsheared viscosity within 30 seconds or even mentions the claimed viscosity levels of 400 to 800 centipoise ("cp"). 281:9-14; 505:4-14.

22. There is no reason to belabor the leaps that Dr. Prud'homme engaged in for his 90%-recovery-in-30-seconds-theory – a theory completely contradicted by both Dr. Lochhead's testing (no recovery in three minutes) and Aventis' own testing with Nasacort AQ. Dr. Klingenberg fully explained the obvious flaws in Dr. Prud'homme's analysis. 502:12-504:16; 505:4-14. But, as just one example, Dr. Prud'homme relied on a jump in viscosity shown at exactly 30 seconds in a 120-second test in Figure 2 of the Hydan report. 254:4-17; 255:17-256:3. But, as Dr. Klingenberg explained, the mere 90 seconds shown following the jump at 30 seconds are not nearly long enough to determine how long it would take the formulations to return to unsheared viscosity. 502:20-503:4. As he also explained, the jump at 30 seconds simply reflects the removal of violent shearing at that point. Such a jump is completely expected and shows nothing about the recovery to unsheared viscosity. 502:12-18.

23. In the end, Aventis' failure to test Barr's product in an appropriate *in vivo* model, by itself, defeats its infringement claims. *Alza*, 464 F.3d at 1295-97.

III. The Patent Specifications Do Not Enable A Skilled Artisan To Make The Claimed Invention.

24. The asserted claims are invalid under 35 U.S.C. § 112 for lack of enablement because the patent specifications do not "teach someone of ordinary skill in the art how to reach the frontal sinus." 406:21-407:2; *Nat'l Recovery Techs. v. Magnetic Separation Sys.*, 166 F.3d 1190, 1196 (Fed. Cir. 1999). A person of ordinary skill in the art is a formulator of nasal dosage forms with an education in pharmaceutical sciences or related fields and direct experience in formulating nasal dosage forms. 402:23-406:2.

25. Unlike any of Aventis' experts, Dr. Donovan is and was a person of ordinary skill. She explained that the patent specifications "don't teach me how to reach the frontal sinus . . . . [T]hey wouldn't have taught me that in 1996. They don't teach me it now even." 407:4-8;

408:6-24 (if there was a way to get a nasal spray to the frontal sinus, she would know about it). Instead, she explained, the patents simply describe a typical nasal formulation, one that uses standard ingredients that match up with prior art products such as Flonase and Beconase AQ. 407:9-19. This would not be enough for her to even begin to make a special nasal spray capable of reaching the frontal sinus. 407:20-23.

26. Aventis did not offer any witness, much less a nasal spray formulator to dispute Dr. Donovan's expert testimony. Her opinion is, thus, uncontroverted.

27. And even if the Court accepted *all* of Aventis' lawyers' arguments – *i.e.*, that Nasacort AQ reaches the frontal sinus in some patients – Aventis' patents would only "enable" a *single* formulation *sometimes* capable of reaching the frontal sinus. That is not sufficient to enable the "*full scope*" of the claims as required by law. *Ormco Corp. v. Align Tech.*, 498 F.3d 1307, 1319 (Fed. Cir. 2007); *Atlas Powder v. E.I. Du Pont De Nemours*, 750 F.2d 1569, 1576-77 (Fed. Cir. 1984). Nasacort AQ uses only one isolated MCC amount (85%, while the claims cover 85 to 95%) and only one isolated shear viscosity (about 60 cp, while the claims cover from 50 to 200 cp). No evidence in the record suggests it is even possible (much less enabled) to make nasal sprays capable of reaching the frontal sinus within the full scope of the claims.

IV. The Asserted Claims Would Have Been Obvious To A Skilled Artisan.

A. The Claimed Elements Were Disclosed In The Prior Art And Obvious.

28. Barr's obviousness defense is similarly uncontroverted. Dr. Thomas Needham, a nasal spray formulator with 40 years of formulation experience in both academia and the pharmaceutical industry, testified that the claimed formulation is a standard formulation using standard ingredients. 588:13-592:5; 593:6-13; 606:14-23; *KSR Int'l v. Teleflex*, 127 S. Ct. 1727, 1740 (2007); *PharmaStem Therapeutics v. ViaCell*, 491 F.3d 1342, 1360 (Fed. Cir. 2007).

29. As Dr. Needham explained, Nasacort AQ itself was disclosed in the prior art as a safe and effective, aqueous-based, thixotropic nasal spray using TAA as an active ingredient. DX10; DX11; 601:7-602:22. While the actual ingredients of Nasacort AQ were not disclosed, the ingredient list virtually matches all of the comparable nasal sprays from the prior art, including Flonase, Beconase AQ and Vancenase AQ. *See* D.I. 163, Appx. A ("SUF") ¶¶ 101-128; 506:1-507:5; 792:9-14.

30. Plainly, it is no "invention" to copy a prior art formulation. As Dr. Needham explained, the "first thing" any formulator would do when making a TAA formulation would be to look at the Physicians' Desk Reference for the ingredient list of the prior art products. 603:6-604:4. That is, in fact, exactly what Aventis did by copying Beconase AQ. DX37; 604:5-605:16.

31. And the only tweak Aventis made – switching out phenylethyl alcohol for EDTA – was no invention either. It was common knowledge in 1995 that those ingredients are interchangeable. As Dr. Needham explained, the substitution of EDTA could not have been more obvious: "All they had to do was look in the Handbook." 622:4-7. That Handbook – the Handbook of Pharmaceutical Excipients – is the most basic treatise for pharmaceutical formulators, and it expressly discloses that *either* EDTA *or* phenylethyl alcohol can be used in combination with benzalkonium chloride to form a preservative system. 608:10-612:18; DX44.

32. Moreover, Barr located *eight* nasal sprays in the prior art that used EDTA rather than phenylethyl alcohol in combination with benzalkonium chloride. 612:25-613:18; SUF ¶¶ 129-132. Using a standard preservative system is simply not a patentable invention. *KSR*, 127 S. Ct. at 1740, 1742.

33. Incredibly, Aventis did not call *any expert* to rebut Dr. Needham's opinion that the claimed invention was exceedingly obvious. Before trial, Aventis had Dr. Lochhead prepare

an expert report arguing that the claimed invention was not obvious. But for some inexplicable reason – perhaps because Dr. Lochhead is not a pharmaceutical formulator, 205:2-4, perhaps because he does not even own the Handbook, 206:21-23, perhaps because his expert report was riddled with mistakes – Aventis chose not to have Dr. Lochhead offer any opinion on obviousness. Thus, Dr. Needham's opinion is uncontroverted.

34. Aventis cannot fill that gaping hole in its evidence by relying on speculation and attorney argument. *CFMT v. Yield Up*, 349 F.3d 1333, 1342 (Fed. Cir. 2003). Aventis' attorneys have argued that the "invention" in this case is that EDTA is "odorless," but that fact was widely-known to pharmaceutical formulators long before 1995, 615:2-21; 617:14-16; DX44; DX62, including the formulators of the eight prior-art nasal sprays that used EDTA.

35. Besides, the fact that EDTA is "odorless" does not distinguish the prior art because phenylethyl alcohol is "odorless" too. It has a *rose scent*, which common experience proves is a *pleasant* scent and, thus, does not cause "user discomfort" as required under the construction of "odorless." 620:8-11; 359:15-360:3; DX51 at 4 (no statistically significant difference in comfort between Nasacort AQ, Flonase or Beconase AQ). In fact, Aventis' patent specification recommends its use. 620:12-621:18; PTX1 at 1:58-60; 6:17-24.

36. Moreover, to the extent Aventis' lawyers argue that Flonase or Beconase AQ causes nasal irritation, they have failed to link any such irritation to the *scent* of phenylethyl alcohol. Indeed, the fact that Flonase was prescribed 3 to 1 over Nasacort AQ demonstrates that Flonase could not have caused user discomfort – a fact that Dr. George Georges conceded could show both patient and doctor preference for Flonase. 548:23-549:2; 68:17-69:2.

37. Even if the scent of phenylethyl alcohol caused any discomfort (which Aventis has not shown), it would still be obvious to substitute EDTA for phenylethyl alcohol, leading to

an entirely expected result of no rose scent. *EMI Grp. N. Am. v. Cypress Semiconductor*, 268 F.3d 1342, 1349 (Fed. Cir. 2001). Aventis has offered no evidence to the contrary.

38. Aventis also cannot claim inventiveness from the use of Avicel CL-611 as the suspending agent rather than Avicel RC-591, which is what is used in Flonase. 624:24-625:2; DX18. Both Avicel grades fall within the claimed ranges and create suspensions with the claimed viscosity profiles. 623:18-624:23; 629:2-13; DX42 at 3; DX34 at 15-16. Moreover, Dr. Klingenberg's testing establishes that Flonase has a shear viscosity within the claimed ranges, 506:1-15, while Dr. Lochhead's contrary results are likely the result of overfilling the container of Flonase – which, like a full ketchup bottle, results in insufficient shearing and artificially high viscosity – or measuring the viscosity of foam. 512:25-513:8; 526:2-15; 540:23-541:13.

39. In any event, Aventis cannot establish nonobviousness from what Dr. Needham testified is routine optimization of the viscosity profile. 622:11-623:12; 625:12-630:3; DX34 at 15; *Pfizer Inc. v. Apotex Inc.*, 480 F.3d 1348, 1368 (Fed. Cir. 2007). Even the patent specification acknowledges that such optimization is routine. PTX1 at 5:10-13; *PharmaStem*, 491 F.3d at 1361-62 (statement that prior art disclosed claimed feature was "binding on patentee for purposes of a later inquiry into obviousness").

40. Aventis also has not shown that its use of Avicel CL-611 provides "a new and unexpected result which is different in kind and not merely in degree from the results of the prior art." *Iron Grip Barbell v. USA Sports*, 392 F.3d 1317, 1322 (Fed. Cir. 2004). Flonase deposits on the same mucosal surfaces and exhibits the same retention and clearance characteristics as Nasacort AQ. 433:4-7; 449:12-451:17. If the Court accepts Dr. Berridge's opinion that Nasacort AQ deposits on the frontal sinus, then so does Flonase. 171:15-24. And if the Court accepts Dr. Prud'homme's opinion that Nasacort AQ returns to unsheared viscosity in the nose,

which is based on the Hydan and FMC reports, then so does Flonase. PTX380; PTX365; 251:14-254:17; 630:12-25; *EMI*, 268 F.3d at 1349 ("Recitation of a law of nature does not distinguish a claim from the prior art."); *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995) (same).

41. In sum, the asserted claims "would be obvious" to a skilled pharmaceutical formulator. 631:1-12. Aventis has offered no competent evidence to the contrary.

B. Aventis' Secondary Considerations Arguments Are Insufficient.

42. None of Aventis' arguments on secondary considerations, on which Aventis bears the burden, overcomes the overwhelming proof that the asserted claims are obvious. *Leapfrog Enters. v. Fisher-Price*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (affirming this Court's obviousness holding despite substantial evidence on secondary considerations).

43. On secondary considerations, Aventis essentially threw mud against the wall, hoping that something would stick. They argued that TAA's "potency" and efficacy were "surprising" compared to fluticasone in Flonase, but TAA's potency and efficacy were *already known* from Nasacort Nasal Inhaler (which used the exact same dosing as Nasacort AQ) and from the Settipane and Kobayashi papers (which also disclosed that Nasacort AQ's dosing was effective). DX10; DX11; 361:18-362:15. Aventis argued that there was a long-felt, unmet need for Nasacort AQ, but offered no supporting testimony and Dr. Mackay (who was in a position to know) testified that there was not. 358:11-359:3; *accord* 360:4-361:16; 817:6-24; 818:20-819:19 (no evidence of improved patient compliance). Moreover, to the extent Aventis contends that Barr copied Nasacort AQ, Barr used that formulation in order to get FDA approval, not because of the patented invention. Zeevi Tr. at 63:4-10, 65:7-66:15; *Eli Lilly & Co. v. Teva Pharms.*, No. IP 02-0512, 2004 WL 1724632, at *38 n.21 (S.D. Ind. July 29, 2004).

44. Aventis' "commercial success" argument falls flat because, in fact, Flonase outsold Nasacort AQ by three to one and there is not one stitch of evidence showing that any

purported "success" enjoyed by Nasacort AQ had any nexus to the patented features rather than from marketing efforts and switching patients from Nasacort Nasal Inhaler. 548-577; 771-783.

V. The Asserted Claims Are Invalid Due To Aventis' Prior Public Use.

45. Finally, Aventis' patents are invalid because the claimed invention was in public use more than a year before the July 3, 1996 application date. 35 U.S.C. § 102(b). "The statutory phrase 'public use' does not necessarily mean open and visible in the ordinary sense; it includes any use of the claimed invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor." *New Railhead Mfg. v. Vermeer Mfg.*, 298 F.3d 1290, 1297 (Fed. Cir. 2002); *Netscape Commc'ns v. Konrad*, 295 F.3d 1315, 1320 (Fed. Cir. 2002). Even a single use by a single third party, and even if the invention is not visible, will be a public use unless the inventor exercises control over the invention and dissemination of information about the invention. *Egbert v. Lippman*, 104 U.S. 333, 336 (1881); *Baxter Int'l. v. COBE Labs.*, 88 F.3d 1054, 1058 (Fed. Cir. 1996).

46. Under that settled standard, the Settipane and Kobayashi studies were public uses. Over 600 patients participated in those clinical trials and used Nasacort AQ from December 1992 to August 1993 with no confidentiality restrictions whatsoever placed on them. 747:4-12. The inventor, Dr. Kim, did not control the off-site studies handled by third parties. 710:2-13. And the patients were free to self-administer Nasacort AQ wherever they pleased, including at work and in public. The patients also knew they were taking an aqueous TAA nasal spray formulation and were free to discuss the nasal spray and the clinical trials with anyone. 709:11-13; 710:14-711:14; 713:3-8; 713:12-14; 740:16-741:20; 742:6-743:22.

47. Moreover, the results of those clinical trials were published in the Settipane and Kobayashi papers over a year before July 3, 1996 and those papers are, themselves, prior art to

the '573 and '329 patents. 743:23-744:8; DX10; DX11; SUF ¶¶ 168-169. And Aventis used those papers in order to market Nasacort AQ. 745:19-746:11; 784:1-16.

48. It is immaterial that the Nasacort AQ ingredient list was not disclosed to the patients. In *New Railhead*, for instance, the Federal Circuit held that using a patented drill bit underground and out of public view was a public use because "it is not public knowledge of [the] invention that precludes the inventor from obtaining a patent for it, but a public use or sale of it." 298 F.3d at 1299 (citations and quotations omitted); *accord Netscape*, 295 F.3d at 1323 (holding that inventor's failure to impose confidentiality restrictions on users placed invention in public use); *Baxter*, 88 F.3d at 1059 ("[L]ack of effort to maintain [the invention] as confidential coupled with the free flow into [the] laboratory of people . . . who observed the [invention] in operation and who were under no duty of confidentiality supports only one conclusion: that the [invention] was in public use."); *MSM Invs. v. Carolwood Corp.*, 70 F. Supp. 2d 1044, 1053 (N.D. Cal. 1999) (patients taking test drug were not bound by confidentiality agreements).

49. Throughout this case, Aventis has been mistakenly relying on the "experimental use" exception to avoid its public use problem. But that exception cannot apply as a matter of black-letter law after the invention is reduced to practice. *New Railhead*, 298 F.3d at 1297; *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1120 (Fed. Cir. 1996); *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1061 (Fed. Cir. 1989). And, Aventis admitted that the claimed invention was reduced to practice as of May 1, 1992 – six months before the clinical trials began. DX284.

CONCLUSION

For the reasons set forth above, Barr is entitled to a judgment in its favor.

May 30, 2008

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on May 30, 2008, I caused to be electronically filed a true and correct copy of the foregoing document, ***Defendant Barr Laboratories, Inc.'s Post-Trial Findings of Fact and Conclusions of Law***, with the Clerk of the Court using CM/ECF, which will send notification of such filing to the following counsel of record:

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